

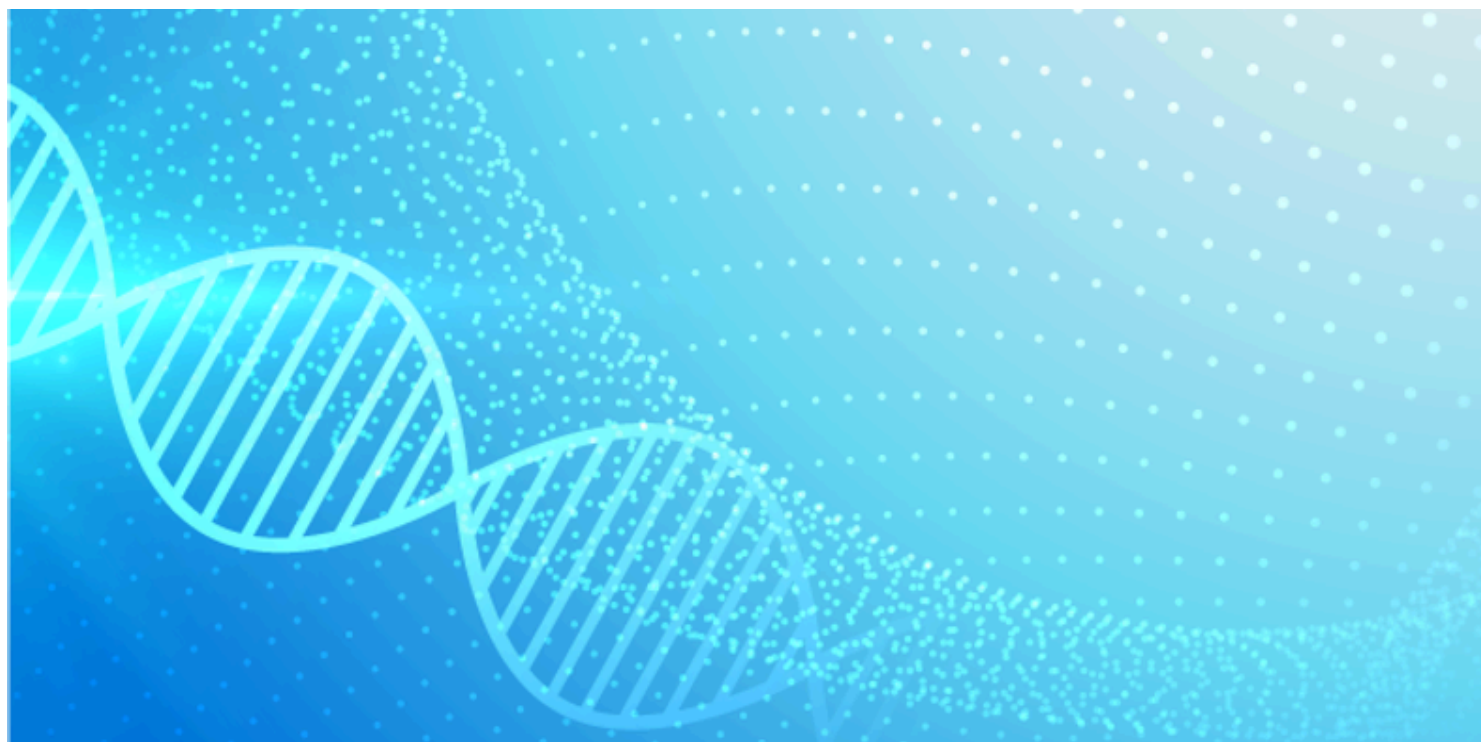
Exhibit 3

Jun 21, 2021

Anavex Life Sciences Announces ANAVEX®2-73 Biomarker Correlated with Efficacy Endpoint in Trial

ANAVEX®2-73 treatment resulted in significant increase in the expression of the SIGMAR1 mRNA biomarker that significantly correlated with improvements in the two primary clinical efficacy endpoints RSBQ ($p = 0.035$) and CGI-I ($p = 0.029$)

Data strengthens milestone to advance regulatory approval pathway for adult patients with Rett syndrome and continued development in other autism spectrum disorders



NEW YORK – June 21, 2021

Anavex Life Sciences Corp. (“Anavex” or the “Company”) (Nasdaq: AVXL), a clinical-stage biopharmaceutical company developing differentiated therapeutics for the treatment of neurodegenerative and neurodevelopmental disorders including Alzheimer’s disease, Parkinson’s disease, Rett syndrome and other central nervous system (CNS) disorders, today reported predictive biomarker of response established with SIGMAR1 mRNA expression correlates significantly with responses in primary clinical efficacy endpoints from the U.S. Phase 2 randomized, double-blind, placebo-controlled trial of ANAVEX®2-73 (*blarcamesine*) in adult female patients with Rett syndrome.

ANAVEX®2-73 activates the sigma-1 receptor (SIGMAR1). Data suggests that activation of SIGMAR1 results in the restoration of complete housekeeping function within the body and is pivotal to restoring neural cell homeostasis and

promoting neuroplasticity. [1] Recent independent findings strengthen the understanding of the beneficial effect of SIGMAR1 activation as compensatory mechanism to chronic CNS diseases. [2]

Rett syndrome is a chronic CNS disease caused by a spontaneous mutation of one gene, MECP2. This study demonstrates for the first-time that a biomarker correlates with clinical efficacy in Rett syndrome. ANAVEX®2-73 treatment resulted in increases in the mRNA expression of SIGMAR1, the gene coding for the receptor targeted by ANAVEX®2-73, which correlated with clinical efficacy as measured by both primary efficacy endpoints (ITT population), namely RSBQ ($p = 0.035$) and CGI-I ($p = 0.029$).

In addition, prespecified patients with WT SIGMAR1 in the clinical trial demonstrated a clinically meaningful and statistically significant 14.5-point ($p = 0.009$) improvement over placebo in the RSBQ total score, the trial's key efficacy endpoint. This magnitude of the improvement with ANAVEX®2-73 compares favorably to published data currently in clinical development, which reported an average difference of 4.4 points in RSBQ total score versus placebo, despite an advantage of higher dose and lower age compared to ANAVEX®2-73-RS-001 trial. [3]

The RSBQ demonstrated balanced improvements across all the instrument's subscales during the trial period of 7 weeks, including general mood, breathing, hand behavior, repetitive face movements, body rocking, night-time behavior, fear/anxiety, walking/standing.

The Anxiety, Depression, and Mood Scale (ADAMS), which is a measure of anxiety and mood symptoms in individuals with intellectual disability,[4] has been clinically validated for use in Rett syndrome[5] and in Fragile X syndrome,[6] demonstrated clinically meaningful and statistically significant 12.9-point ($p = 0.005$) improvement for ANAVEX®2-73 treated adult patients with Rett syndrome vs placebo in prespecified patients with WT SIGMAR1.

The ADAMS also demonstrated balanced improvements across all different subscales during the trial period of 7 weeks, including manic/hyperactive behavior, depressed mood, social avoidance, general anxiety, obsessive compulsive behavior.

"The biomarker-driven clinical evidence is very exciting and opens the possibility of successful treatment for both adults and children with Rett syndrome and early interventions for modifying the course of the disease," commented Walter E. Kaufmann, MD, Principal Investigator and Chief Medical Officer of Anavex. "The outcome of this trial is very promising in terms of both safety and clinical improvement. Despite the challenges of the older age of the cohort (patients were on average 24 years of age) and the relatively low dose (5 mg daily), ANAVEX®2-73 demonstrated clinically meaningful improvements in outcome measures evaluating multiple impairments, which are supported by correlations with objective biomarkers."

With this convincing biomarker correlating efficacy data of U.S. Phase 2 (ANAVEX®2-73-RS-001)[7] study in adult patients with Rett syndrome, Anavex is planning to meet with the FDA to discuss the approval pathway. There are no FDA-approved drugs for Rett syndrome. ANAVEX®2-73 has Fast Track designation, Rare Pediatric Disease designation and Orphan Drug designation from the FDA for the treatment of Rett syndrome and may be considered for accelerated approval. The study was supported by the Rettsyndrome.org Foundation.

ANAVEX®2-73 is currently being evaluated for Rett syndrome in two other ongoing late-stage placebo-controlled clinical studies: The AVATAR trial in adult Rett syndrome (ANAVEX®2-73-RS-002)[8] and the EXCELLENCE pediatric Rett syndrome trial (ANAVEX®2-73-RS-003)[9].

“These are strong and consistent data demonstrating biomarker-correlated rapid and clinically meaningful improvements in key measures of Rett syndrome symptoms in the ANAVEX®2-73 treatment group compared to placebo,” said Christopher U. Missling, PhD, President & Chief Executive Officer of Anavex. “Our team is dedicated to provide for this urgent unmet need of patients with Rett syndrome, and we believe our ANAVEX®2-73 Rett syndrome program sets us on a course to potentially offer a new, unique and mechanistically differentiated treatment option also for other diseases associated with autism spectrum disorder.”

Anavex Life Sciences’ product portfolio platform includes small molecule drug lead candidate ANAVEX®2-73 for the treatment of Alzheimer’s disease, Parkinson’s disease and Rett syndrome and ANAVEX®3-71 for frontotemporal dementia.

About Rett Syndrome

Rett syndrome is a devastating, non-inherited genetic post-natal progressive neurodevelopmental disorder that occurs almost exclusively in girls and leads to severe impairments, affecting nearly every aspect of the child’s life: their ability to speak, walk, eat and easily breathe. The hallmark of Rett syndrome is near constant repetitive hand movements while awake. The disease is characterized by normal early growth and development (6 to 18 months) followed by a slowing of development, loss of purposeful use of the hands, distinctive hand movements, autistic features, slowed brain and head growth, ataxia, seizures, and intellectual disability.

Rett syndrome is caused by mutations in the *MECP2* gene and strikes all racial and ethnic groups. The disease occurs worldwide in approximately one in every 10,000 to 15,000 live births. The population of patients with Rett syndrome is estimated to be approximately 11,000 patients in the U.S. There is currently no cure for Rett syndrome.

About ANAVEX®2-73-RS-001 Clinical Study (NCT03758924)

The Phase 2 trial is a randomized double-blind, placebo-controlled safety, tolerability, pharmacokinetic and efficacy study of oral liquid ANAVEX®2-73 to treat Rett syndrome in a total of 31 adult patients with Rett syndrome over a 7-weeks treatment period (End of Trial, EOT) were evaluated incorporating precision medicine biomarkers. Preceding the placebo-controlled randomization of 25 patients (Part B), a 6-patient cohort (Part A) underwent a 7-weeks pharmacokinetic (PK) assessment with safety, tolerability, pharmacokinetic and efficacy evaluation of ANAVEX®2-73. All patients who participated in the study were eligible to receive ANAVEX®2-73 under an open label extension protocol.

The primary endpoint of the trial was safety. The convenient oral liquid once-daily dosing of 5 mg ANAVEX®2-73 was well-tolerated and demonstrated dose-proportional PK (pharmacokinetics). Adverse events related to study drug were similar between ANAVEX®2-73 (13.3%) and placebo (10%), with no reported serious adverse events (SAEs). The safety profile of ANAVEX®2-73 in this trial is consistent with prior clinical trial data.

All secondary efficacy endpoints of the trial showed statistically significant and clinically meaningful sustained improvements for ANAVEX®2-73 compared to placebo, consisting of the Rett Syndrome Behaviour Questionnaire (RSBQ) ($p = 0.048$) and the Clinical Global Impression Improvement Scale (CGI-I) score ($p = 0.014$) in the intent-to-treat

(ITT) population (n = 25). Statistically significant differences in patient symptoms between the active and placebo groups occurred as early as 4 weeks following the initiation of ANAVEX®2-73 administration.

About Rettsyndrome.org

Rettsyndrome.org is the most comprehensive nonprofit organization dedicated to accelerating research of treatments and a cure for Rett syndrome and related disorders while providing information and family empowerment. As the world's leading private funder of Rett syndrome research, Rettsyndrome.org has funded over \$40M in high-quality, peer-reviewed research grants and programs to date. The organization hosts the largest global gathering of Rett researchers and clinicians to establish research direction for the future. Rettsyndrome.org, a 501(c)(3) organization, has earned Charity Navigator's most prestigious 4 star rating year after year. To learn more about our work and Rett syndrome, visit www.rettsyndrome.org or call (800) 818-7388 (RETT).

About Anavex Life Sciences Corp.

Anavex Life Sciences Corp. (Nasdaq: AVXL) is a publicly traded biopharmaceutical company dedicated to the development of differentiated therapeutics for the treatment of neurodegenerative and neurodevelopmental disorders including Alzheimer's disease, Parkinson's disease, Rett syndrome and other central nervous system (CNS) diseases, pain and various types of cancer. Anavex's lead drug candidate, ANAVEX®2-73 (*blarcamesine*), successfully completed a Phase 2a clinical trial for Alzheimer's disease and recently a Phase 2 proof-of-concept study in Parkinson's disease dementia and a Phase 2 study in adult patients with Rett syndrome. ANAVEX®2-73 is an orally available drug candidate that restores cellular homeostasis by targeting sigma-1 and muscarinic receptors. Preclinical studies demonstrated its potential to halt and/or reverse the course of Alzheimer's disease. ANAVEX®2-73 also exhibited anticonvulsant, anti-amnesic, neuroprotective and anti-depressant properties in animal models, indicating its potential to treat additional CNS disorders, including epilepsy. The Michael J. Fox Foundation for Parkinson's Research previously awarded Anavex a research grant, which fully funded a preclinical study to develop ANAVEX®2-73 for the treatment of Parkinson's disease. ANAVEX®3-71, which targets sigma-1 and muscarinic receptors, is a promising clinical stage drug candidate demonstrating disease-modifying activity against the major hallmarks of Alzheimer's disease in transgenic (3xTg-AD) mice, including cognitive deficits, amyloid and tau pathologies. In preclinical trials, ANAVEX®3-71 has shown beneficial effects on mitochondrial dysfunction and neuroinflammation. Further information is available at www.anavex.com. You can also connect with the company on [Twitter](#), [Facebook](#), [Instagram](#) and [LinkedIn](#).

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks set forth in the Company's most recent Annual Report on Form 10-K filed with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Anavex Life Sciences Corp. undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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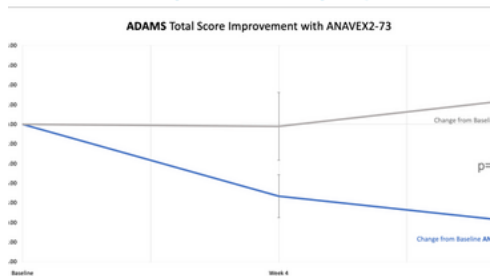
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- [2] Prasanth MI, Malar DS, Tencomnao T, Brimson JM. The emerging role of the sigma-1 receptor in autophagy: Hand-in-hand targets for the treatment of Alzheimer's. Expert Opin Ther Targets. 2021 Jun 10. doi: 10.1080/14728222.2021.1939681. Epub ahead of print. PMID: 34110944.
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- [6] Cordeiro L, Ballinger E, Hagerman R, Hessel D. Clinical assessment of DSM-IV anxiety disorders in fragile X syndrome: prevalence and characterization. J Neurodev Disord. 2011;3:57-67. doi: 10.1007/s11689-010-9067-y. Epub 2010 Dec 3.
- [7] ClinicalTrials.gov Identifier: NCT03758924
- [8] ClinicalTrials.gov Identifier: NCT03941444
- [9] ClinicalTrials.gov Identifier: NCT04304482

ADAMS Total Score

Clinically Validated Efficacy Endpoint

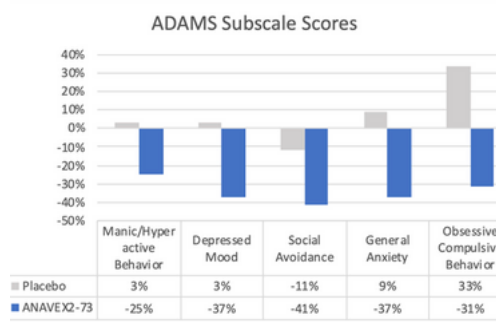


meaningful and statistically significant Improvement for ANAVEX2-73 with Rett syndrome vs placebo

improvement at Week 7 with p=0.005 (-10.10 ANAVEX2-73 vs. 2.75

ADAMS Subscale Scores

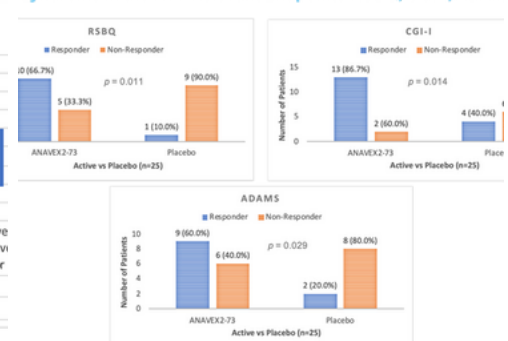
and Balanced Improvements across all Subscales (observed a



Cohen's d effect size of 1.31

e 2: Improvement in All Key Don

ment Resulted in a Statistically Significant Improvement for / Syndrome in the RTT-Relevant Endpoints RSBQ, CGI-I, ADAM



X2-73 and 10 on Placebo) sion of the disease and treatment effect over the course of the study

fficacy Already at Low ANAVEX[®] ne Behaviour Questionnaire (RSBQ

Prespecified Primary Efficacy Endpoint

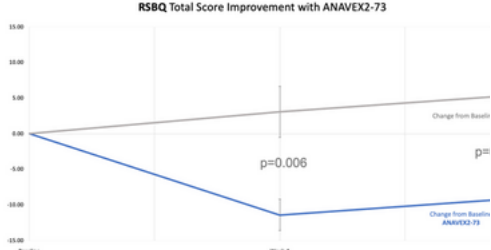
RSBQ Subscale Scores

and Balanced Improvements across all Subscales (observed a

	Estimated Difference between Active and Placebo	Age, y median
Low	-14.5	24.00
High	-4.4	9.41
Weighted		

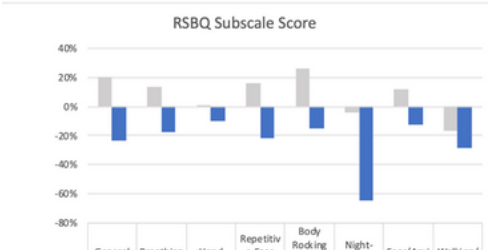
Phase 2 RSBQ Total Score compares favorably with other published data in Rett syndrome and older patient cohort

¹ n = 14)
Kravitz E, Condon S, Storms G, Oosterhoff S, Della Pasqua O, Glass L, Jones NE, Percy AK; Rett 002 Study Group. Rett syndrome. *Neurology*. 2019 Apr 16;92(16):e1912-e1925. doi: 10.1212/WNL.0000000000007316. Epub 2019 Apr 16.



meaningful and statistically significant improvement for ANAVEX[®]2-73 in Rett syndrome vs placebo

improvement at Week 7 with p=0.009 (-8.92 ANAVEX[®]2-73 vs. 5.56 placebo) at every assessed time point



	General Mood	Breathing Problems	Hand Behaviors	Repetitive Face Movements	Body Rocking and Expressionless Face	Night-time Behaviors	Fear/Anxiety	Walking/Standing
Placebo	20%	14%	1%	16%	26%	-4%	12%	-16%
ANAVEX2-73	-23%	-18%	-10%	-22%	-15%	-65%	-12%	-28%

Cohen's d effect size of 1.11